- Institutional Certification for Human Genomic Data Sharing. If the proposed project involves a genomic data sharing plan for the generation of human genomic data, investigators must submit an Institutional Certification, or, in some cases, a Provisional Institutional Certification. Institutional certification forms and directions for completing them are available on the NIH GDS: <u>http://gds.nih.gov/Institutional_Certifications.html</u>. This certification should be submitted as an "Other Upload" in the eRA Commons Just-in-Time module.
- SBIR Funding Agreement Certification. For SBIR applicants, provide only upon request the SBIR Funding Agreement Certification described in Section 2.18. This certification is available in fillable format on the SBIR/Forms website: http://grants.nih.gov/grants/forms.htm#sbir. This should be submitted as an "Other Upload" in the eRA Commons Just-in-Time module.
- STTR Funding Agreement Certification. For STTR applicants, provide only upon request the STTR Funding Agreement Certification described in Section 2.19. This certification is available in fillable format on the SBIR/Forms website: http://grants.nih.gov/grants/forms.htm#sbir. This should be submitted as an "Other Upload" in the eRA Commons Just-in-Time module.
- Other Information Requested by the Awarding IC: Additional JIT information (i.e., revised budgets, changes to the human subjects, or vertebrate animal sections of the application) may be requested by NIH Institutes and/or Centers on a case-by-case basis. These should be submitted as an "Other Upload" file.

Applicants will be notified (primarily by e-mail) when Just-in-Time information is needed. This notification is not a Notice of Award nor should it be construed to be an indicator of possible funding. Applicants should only submit this information when requested. In some circumstances the GMO may ask for information in addition to the descriptions above. Information must be submitted electronically using the Just-in-Time feature in the eRA Commons. For information on the Commons see: <u>https://commons.era.nih.gov/ commons/index.jsp</u>.

The requirement for applicants to verify the accuracy and validity of all administrative, fiscal, and programmatic information extends to information submitted through the Just-in-Time process. Applicants are responsible for promptly notifying NIH of any substantive changes to previously submitted Just-in-Time information up to the time of award. This includes items such as Other Support changes that could lead to budgetary overlap, scientific overlap, or commitment of effort greater than 12 person-months for the PD/PI(s) or any Senior/Key Personnel; or any changes in the use or approval of vertebrate animals or human subjects. Similar to the NIH public policy requirements, applicants are responsible for establishing and maintaining the necessary processes to monitor its compliance and informing NIH of any problems or concerns. Failure to address changes to Just-in-Time submissions prior to award does not diminish the applicant's responsibility to address changes post-award by submitting a prior approval request to NIH.

1.8 Other Support

Do not submit information on Other Support with the application beyond that required in the biographical sketch. See <u>1.7 Just-in-Time Policy</u>.

Information on Other Support is required for all applications that are to receive grant awards, except Program Directors, training faculty and other individuals involved in the oversight of training grants. NIH will request complete and up to date information from applicants at an appropriate time *after peer review*. The Institute/Center scientific program and grants management staff will review this information prior to award.

Do not confuse Research Support with Other Support, they are distinctly different. As part of the biosketch section of the application, Research Support highlights your accomplishments, and those of your colleagues, as scientists. This information will be used by the reviewers in the assessment of each individual's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualification of the research team. In

Supplemental Instructions for PHS 398 and SF424 (R&R)

contrast, Other Support information is required for all applications that are selected to receive grant awards and includes detailed financial information. NIH staff will request complete and up-to-date "Other Support" information *after* peer review. This information will be used to check that the proposed research is not already funded through other sources.

Information on Other Support is also required in the progress report for all senior/key personnel, excluding consultants, when there has been a change in active other support. Other Support is not required in progress reports for Program Directors, training faculty, and other individuals involved in the oversight of training grants.

Other Support Policy

Other Support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. Training awards, prizes, or gifts are not included.

Information on Other Support assists awarding agency staff in the identification and resolution of potential overlap of support. Overlap, whether scientific, budgetary, or commitment of an individual's effort greater than 100 percent (i.e., 12 person months), is not permitted. The goals in identifying and eliminating overlap are to ensure that sufficient and appropriate levels of effort are committed to the project; that there is no duplication of funding for scientific aims, specific budgetary items, or an individual's level of effort; and that only funds necessary to the conduct of the approved project are included in the award.

Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salary) are requested in an application but are already provided for by another source.

Commitment overlap occurs when a person's time commitment exceeds 100 percent (i.e., 12 person months), whether or not salary support is requested in the application. While information on other support is only requested for senior/key personnel (excluding consultants), no individuals on the project may have commitments in excess of 100 percent or 12 person months.

Scientific overlap occurs when: (1) substantially the same research is proposed in more than one application or is submitted to two or more different funding sources for review and funding consideration, or (2) a specific research objective and the research design for accomplishing that objective are the same or closely related in two or more applications or awards, regardless of the funding source. Potential scientific overlap is to be addressed by the SRG *only* by its identification in an Administrative Note in the Summary Statement.

Resolution of Overlap. Resolution of overlap occurs at the time of award in conjunction with applicant institution officials, the PD/PI, and awarding agency staff.

Other Support Information

Information on Other Support for competing applications should be submitted ONLY when requested by the NIH Institute/Center (IC).

There is no form page for Other Support. Follow the sample format provided below. The sample is intended to provide guidance regarding the type and extent of information requested.

Follow the instructions below to complete the other support:

• Other Support for Competing Applications: Information on active and pending Other Support is required for senior/key personnel, excluding consultants. For individuals with no active or pending support, indicate "None." Neither the application under consideration nor the current PHS award for this project should be listed as Other Support. Do not include Other Support for individuals listed as "Other Significant Contributors" unless their involvement has changed so that they now meet the definition of "senior/key personnel." If the support is provided under a consortium/contractual arrangement or is part of a multiproject award, indicate the project number, PD/PI, and source for the overall project, and provide all other information for the subproject only.

• Other Support for Progress Reports: Information should be submitted only for the PD/PI and for those individuals considered by the grantee to be key to the project when there has been a change in active other support. Indicate what the change has been. List the award for which the progress report is being submitted and include the effort that will be devoted in the next reporting period. Do not include Other Support for individuals listed as "Other Significant Contributors" unless their involvement has changed so that they now meet the definition of "senior/key personnel." Submission of other support information is not necessary if support is pending or for changes in the level of effort for active support reported previously.

Instructions for Selected Items

Project Number: If applicable, include a code or identifier for the project.

Source: Identify the agency, institute, foundation, or other organization that is providing the support. Include institutional, federal, public, and private sources of support.

Major Goals: Provide a brief statement of the overall objectives of the project, subproject, or consortium/contractual arrangement.

Dates of Approved/Proposed Project: Indicate the inclusive dates of the project as approved/proposed. For example, in the case of NIH support, provide the dates of the approved/proposed competitive segment.

Annual Direct Costs: In the case of an active project, provide the current year's direct cost budget. For a pending project, provide the proposed direct cost budget for the initial budget period.

Percent Effort/Person Months: For an active project, provide the level of actual effort in person months (even if unsalaried) for the current budget period. Person months should be classified as academic, calendar and/or summer. For a pending project, indicate the level of effort in person months as proposed for the initial budget period. In cases where an individual's appointment is divided into academic and summer segments, indicate the proportion of each devoted to the project.

Overlap: After listing all support, summarize for each individual any potential overlap with the active or pending projects and this application in terms of the science, budget, or an individual's committed effort.

Sample Format for Other Support for Competing Applications

For New and Renewal Applications (PHS 398) - DC	NOT SUBMIT UNLESS REQ	JESTE	D
	HER SUPPORT		
Provide active and pending support for all senior/key personnel. Other Sup commercial or institutional, available in direct support of an individual cooperative agreements, contracts, and/or institutional awards. Trainin There is no "form page" for other support. Information on other support shoun ecessary. The sample below is intended to provide guidance regarding the For instructions and information pertaining to the use of and policy for other Policies, Assurances, Definitions, and Other Information.	's research endeavors, including but not g awards, prizes, or gifts do not need to be uld be provided in the <i>format</i> shown below, e type and extent of information requested. support, see Other Support in the Supplem	limited t included. using con ental Inst	o research grants, tinuation pages as ructions, Part III,
Effort devoted to projects must be measured using person months. Indicate		IS associa	ted with each project.
4 1954	rmat		
NAME OF INDIVIDUAL ACTIVE/PENDING			
Project Number (Principal Investigator) Source Title of Project (or Subproject)	Dates of Approved/Proposed Project Annual Direct Costs		Person Months (Cal/Academic/ Summer)
The major goals of this project are OVERLAP (summarized for each individual)			
	nples		
ANDERSON, R.R.			
ACTIVE	0///0010 0/00/0017		1000 • 10000 • 1000
2 R01 HL 00000-13 (Anderson) NIH/NHLBI Chloride and Sodium Transport in Airway Epithelial	3/1/2012 – 2/28/2017 \$186,529 Cells	3.60	calendar
The major goals of this project are to define the bio epithelial cells and clone the gene(s) involved in tra		m trans	port in airway
5 R01 HL 00000-07 (Baker) NIH/NHLBI	4/1/2001 – 3/31/2012 \$122,717	1.20	calendar
Ion Transport in Lungs			
The major goal of this project is to study chloride an	nd sodium transport in normal a	nd dise	ased lungs.
R000 (Anderson) Cystic Fibrosis Foundation Gene Transfer of CFTR to the Airway Epithelium	9/1/2014 – 8/31/2017 \$43,123	1.20	calendar
The major goals of this project are to identify and is human CFTR in airway epithelial cells.	olate airway epithelium progeni	tor cells	s and express
PENDING			
DCB 950000 (Anderson) National Science Foundation	12/1/2014 – 11/30/2016 \$82,163	2.40	calendar
Liposome Membrane Composition and Function			
The major goals of this project are to define biocher and maximize liposome uptake into cells.	mical properties of liposome me	mbran	e components

p53 Mutations in Breast Cancer

progression and metastasis.

BE 00000 (Hernandez)

American Cancer Society

5 P01 CA 00000-03 (Chen)

OMB No. 0925-0001 (Rev. 06/15 Approved Through 10/31/2018)

5 R01 CA 00000-07 (Hernandez)

Gene Therapy for Small Cell Lung Carcinoma

cell lines and to study the effect on growth and invasiveness of the lines.

Mutations in p53 in Progression of Small Cell Lung Carcinoma

The major goals of this project are to define the spectrum of p53 mutations in human breast cancer samples and correlate the results with clinical outcome.

There is scientific overlap between aim 2 of NSF DCB 950000 and aim 4 of the application under consideration. If both are funded, the budgets will be adjusted appropriately in conjunction with agency

4/1/2010 - 3/31/2017

7/1/2014 - 6/30/2016

\$104,428 (sub only)

9/1/2014 - 8/31/2017

\$86,732

\$110,532

The major goals of this project are to use viral strategies to express the normal p53 gene in human SCLC

The major goals of this subproject are to define the p53 mutations in SCLC and their contribution to tumor

3.60 academic

1.80 academic

1.80 academic

3.00 summer

OVERLAP

OVERLAP

staff.

ACTIVE

RICHARDS, L. NONE

HERNANDEZ, M.

NIH/NCI

NIH/NCI

Potential commitment overlap for Dr. Hernandez between 5 R01 CA 00000-07 and the application under consideration. If the application under consideration is funded with Dr. Hernandez committed at 3.60 person months, Dr. Hernandez will request approval to reduce her months on the NCI grant.

BENNETT, P.

ACTIVE

Investigator Award (Bennett) Howard Hughes Medical Institute Gene Cloning and Targeting for Neurological Disease Genes This award supports the PI's program to map and clone the gene(s) implicated in the development of Alzheimer's disease and to target expression of the cloned gene(s) to relevant cells.

OVERLAP: None

Other Support Format Page

Sample Format for Other Support for Progress Reports

OMB No. 0925-0002 (Rev. 06/15 Approved Through 10/31/2018)

PHS 2590/RPPR OTHER SUPPORT FORMAT PAGE

Submit other support for all new senior/key personnel, and updated other support for all senior/key personnel for whom there has been a change since the last reporting period.

Provide only active support for all new senior/key personnel. Provide updated other supported for all senior/key personnel for whom there has been a change in other support. If a previously active grant has terminated and/or if a previously pending grant is now active, update by annotating accordingly.

Other Support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. Training awards, prizes, or gifts do not need to be included. Effort devoted to projects must be reported in person months; indicate calendar, academic, and/or summer months associated with each project.

Use the suggested format shown below and continuation pages as necessary. The sample format below provides guidance regarding the type and extent of information that should be provided.

	Format	
ACTIVE/INACTIVE		
Project Number or Name (PD/PI name)	Dates of Approved/Proposed Proje	ect Person Months
Source of Support Title of Project or Subproject	Annual Direct Costs	(Calendar/Academic/ Summer)
The major goals of this project are		
OVERLAP (summarized for each individual)	•	
E	xamples	
NEW SENIOR/KEY PERSONNEL (D.2.b)		
BENNETT, P.		
ACTIVE		
Investigator Award (Bennett)		5.0 calendar
Howard Hughes Medical Institute	\$581,317	
Gene Cloning and Targeting for Neurological Dis		
This award supports the PI's program to map an Alzheimer's disease and to target expression of		levelopment of
5 R01 HG 000000-07 (Daumier)		6.6 calendar
NIH/NHGRI Identification of the Risk Factor Genes for Alzhe	\$196,639 imer's Disease	
The major goals of this project are to identify of r disease.	new Alzheimer's disease genes and pr	edicting Alzheimer's
(THIS AWARD) 2 R01 HL 000000-14 (Anderson)	3/1/2002 - 2/28/2017 1	.2 calendar
NIH/NHLBI	\$186.529	.2 Calendar
Chloride and Sodium Transport in Airway Epithe		
OVERLAP No Overlap		
RICHARDS, L.		
No Other Support		
	Page 0	Other Support Format Page

NDERSON, R.R.						
(THIS AWARD) 2 R01 HL 000000-14 (Anderson)	3/1/2002 - 2/28/2017	3.6 calendar				
NIH/NHLBI Chloride and Sodium Transport in Airway E	\$186,529					
The major goals of this project are to define epithelial cells and clone the gene(s) involv		ium transport in airway				
5 R01 HL 00000-04 (Baker) NIH/NHLBI Ion Transport in Lungs	4/1/2012 – 3/31/2016 \$122,717	1.2 calendar				
The major goal of this project is to study ch	The major goal of this project is to study chloride and sodium transport in normal and diseased lungs.					
R000 (Anderson) Cystic Fibrosis Foundation Gene Transfer of CFTR to the Airway Epith	9/1/2001 – 8/31/2016 \$43,123 nelium	1.2 calendar				
The major goals of this project are to identi human CFTR in airway epithelial cells.	fy and isolate airway epithelium proge	nitor cells and express				
(NEW) R01 DK000000-01 (Zimmerman) NIH/NIDDK Cystic Fibrosis Related Diabetes and Lung	9/1/2015 – 8/31/2019 \$187,265 Function	1.2 calendar				
The major goals of this project are to deter	mine how CFRD contributes to lung fu	nction decline.				
OVERLAP No Overlap						
NACTIVE						
DCB 950000 (Anderson) National Science Foundation Liposome Membrane Composition and Fur	12/1/2008 – 11/30/2011 \$82,163 nction	2.4 calendar				
The major goals of this project are to define and maximize liposome uptake into cells.	e biochemical properties of liposome n	nembrane components				
IERNANDEZ, M. ACTIVE						
5 R01 CA 00000-08 (Hernandez) NIH/NCI Gene Therapy for Small Cell Lung Carcino	4/1/2007 – 3/31/2017 \$110,532 ma	3.6 academic 3.0 summer				
The major goals of this project are to use v cell lines and to study the effect on growth	iral strategies to express the normal p	53 gene in human SCLC				

 OMB No. 0925-0002 (Rev. 06/15 Approved Through 10/31/2018) (NEW)
 7/1/2011 – 6/30/2016
 1.8 academic

 5 P01 CA 00000-02 (Chen)
 7/1/2011 – 6/30/2016
 1.8 academic

 NIH/NCI
 \$104,428 (sub only)

 Mutations in p53 in Progression of Small Cell Lung Carcinoma

The major goals of this subproject are to define the p53 mutations in SCLC and their contribution to tumor progression and metastasis.

BE 00000 (Hernandez)	9/1/1999 - 8/31/2016	1.8 academic
American Cancer Society	\$86,732	
p53 Mutations in Breast Cancer		

The major goals of this project are to define the spectrum of p53 mutations in human breast cancer samples and correlate the results with clinical outcome.

 (THIS AWARD)

 2 R01 HL 000000-13 (Anderson)
 3/1/2002 – 2/28/2017

 NIH/NHLBI
 \$186,529

 Chloride and Sodium Transport in Airway Epithelial Cells

<u>OVERLAP</u> There was scientific overlap between aim 2 of 5 R01 CA 00000-08 and aim 4 of project 2 in 5 P01 CA 00000-02. In conjunction with agency staff, it was decided to remove aim 4 of project 2 from the P01 and adjust the budget and PI level of effort accordingly.

Page ___

Other Support Format Page

0.6 calendar